REMARKS

Favorable reconsideration and continued examination of the present application are respectfully requested.

Applicants gratefully acknowledge the indication at pages 9 and 10 of the December 3, 2002 Office Action that claims directed to bone resorption inhibitor compositions comprising the polypeptide of SEQ ID NO. 1 and methods of administering same to achieve bone resorption inhibition would be allowable. Applicants also gratefully acknowledge the indication at page 10 of the Office Action that methods of administering the polypeptide of SEQ ID NO. 1 to an animal in an amount effective to achieve inhibition of bone resorption would be allowable.

The amendment to the claims and the new claims are fully supported in the present application. For example, see pages 3, 6, 7, 8, and 9 and the claims as originally filed and the sequence listing. The sequence listing, in particular Seq. ID NO. 2, is the same as Seq. ID NO. 1, with Xaa=Ile. Accordingly, no questions of new matter should arise, and entry of the amendment is respectfully requested. The Examiner will note that essentially the claims are directed to the subject matter indicated as allowable.

Response To The Rejection Of Claims 1-4 And 8-10 Under 35 U.S.C. § 101

Claims 1-4 and claims 8-10 are rejected under 35 U.S.C. § 101. The Examiner alleges that the claims are unclear as to whether the claims are directed to a compound or to a composition containing the compound. For the following reasons, this rejection is respectfully traversed.

The claims are directed to a composition containing compounds as described. Applicants have amended claims 1-4 and 8-10 to include the word "composition." The Applicants maintain

that original claims 1-4 and 8-10 are directed to statutory subject matter. This amendment does not alter the scope of the claim and does not introduce new matter and is supported by the application, for example, at page 6, line 24 through page 7, line 5. Accordingly, the rejection should be withdrawn.

Claims 1-10 are rejected under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. Specifically, the Examiner states that it is unclear whether claims 1-4 and 8-10 are directed to bone resorption inhibitor compounds or compositions. The Examiner states that claim 2 recites amino acid positions without any reference to a sequence. The Examiner also states that claim 5 does not clearly recite a method step and that it merely recites an unpatentable determination step that is part of a mental process. The Examiner states that in claim 6, it is unclear what the factor or factor-derived substances are added to. The Examiner also alleges that in claim 7 there is no recitation that the factor or factor-derived substances are present in an amount effective to achieve inhibition of bone resorption and, therefore, the method step does not clearly relate back to the goal set forth in the preamble. For the following reasons, this rejection is respectfully traversed.

The Applicants do not believe that the original claims 1-10 were indefinite. To assist the Examiner and to clarify the claims, the Applicants have amended claims 1-4 and 8-10 to more particularly point out and more distinctly claim the subject matter that Applicants regard as the invention by including the word "composition." Applicants have also amended claims 1 and 2 to identify the leukocyte activating protein factor or leukocyte activating protein factor-derived substances as having an amino acid sequence containing some or all of the sequence of SEQ ID

NO. 2. Applicants have amended claim 5 to more distinctly recite a method step and to more clearly define the subject matter that Applicants regard as the invention. Applicants have amended claim 6 by further clarifying the role of leukocyte activating protein factor or leukocyte activating protein factor-derived substances in the production of bone resorption inhibitors. Applicants have amended claim 7 to clarify that an effective amount of bone resorption inhibitor is administered to achieve inhibition of bone resorption. Accordingly, the rejection should be withdrawn.

Response To The Rejection Of Claims 1-10 Under 35 U.S.C. § 112, First Paragraph

Claims 1-10 are rejected under 35 U.S.C. § 112, first paragraph. The Examiner states that the specification does not reasonably provide enablement for other proteins or substances derived from SEQ ID NO. 1, as claimed. The Examiner states that Applicants have provided little or no guidance beyond the mere presentation of sequence data to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the protein that are tolerant to change, for example, by substitution or deletion of amino acids, and the nature and extent of changes that can be made in these positions. The Examiner further states that undue experimentation would be required to make and/or use the claimed invention because of the large quantity of experimentation required to generate the infinite number of derivatives recited in the claims and to screen those derivatives for activity, the lack of direction or guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art that establishes the unpredictability of the effects of mutation on protein structure

and function, and the breadth of the claims that fail to recite any structural limitations.

Claims 1-10 are also rejected under 35 U.S.C. § 112, first paragraph. The Examiner states that the specification does not reasonably convey to one skilled in the art that Applicants had possession of the claimed invention at the time the application was filed. The Examiner states that the claims are directed to leukocyte activating protein factor-derived substances without any structural limitations while only isolated polypeptides having the amino acid sequence set forth in SEQ ID NO. 1 meet the written description provision of 35 U.S.C. § 112, first paragraph. For the following reasons, the rejections are respectfully traversed.

The claims recite substances having SEQ ID NO. 1 or NO. 2. The Applicants believe that original and pending claims 1, 2, 5, 6, and 7 and the claims that depend therefrom are clearly enabled. The specification clearly shows this enablement. Accordingly, the rejection should be withdrawn.

Response To The Rejection Of Claims 1-4 And 6-10 Under 35 U.S.C.§ 102

Claims 1-4 and 6-10 are rejected under 35 U.S.C. § 102(b) on the basis of EP 0 723 016 A2 (hereinafter "the EP reference"). The Examiner asserts that the document discloses the polypeptide LECT2 of SEQ ID No. 1. Therefore, the Examiner rejects Claims 1-4 and 8-10 for claiming a bone resorption inhibitor encompassing the polypeptide of SEQ ID NO. 1. Claims 6 and 7 are rejected because the phrase "bone resorption inhibitor" was interpreted as an intended use and therefore no patentable weight was given to the phrase. For the following reasons, this rejection is respectfully traversed.

The invention recites bone resorption inhibitors having a SEQ ID NO. 2. SEQ ID NO. 2

is not disclosed by the EP reference. Claim 6 is also not taught or suggested by the EP reference. The EP reference does not disclose using leukocyte activating protein factor or leukocyte activating protein factor-derived substances in the production of bone resorption inhibitors. Claim 7 is also not taught or suggested by the EP reference. The cited art does not disclose administering to an animal an effective amount of bone resorption inhibitor derived substances containing leukocyte activating protein factor or leukocyte activating protein factor-derived substances. Accordingly, the rejection should be withdrawn.

Deletion Of Current Sequence Listing And Insertion Of Substitute Sequence Listing

The Applicants deleted the current sequence listing and inserted a substitute sequence listing. The amendment does not introduce new matter, and is supported by the application, for example, at SEQ ID NO. 1.

The diskette enclosed herewith contains a computer readable form of the Sequence Listing for the above-referenced patent application. The information recorded in computer readable form on the diskette is identical to the written sequences contained in the application and to the paper copy of the Sequence Listing filed herewith. The computer readable form of the sequence listing contained on this diskette complies with the requirements of 37 C.F.R. § 1.821 et seq.

CONCLUSION

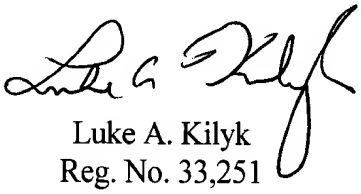
In view of the foregoing remarks, Applicants respectfully request the reconsideration of this application and the timely allowance of the pending claims.

Should the Examiner deem that any further action by applicants or applicants'

representatives is desirable and/or necessary, the Examiner is invited to telephone applicants' representatives at the number set forth below.

If there are any other fees due in connection with the filing of this response, please charge the fees to deposit Account No. 50-0925. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such extension is requested and should also be charged to said Deposit Account.

Respectfully submitted,



Luke A. Kilyk
Reg. No. 33,251

Atty. Docket No. 3190-010
KILYK & BOWERSOX, P.L.L.C.
53A East Lee Street
Warrenton, Virginia 20186
Tel.: (540) 428-1701
Fax.: (540) 428-1720

Enclosures: Computer Diskette
Paper Copy of Sequence Listing
Appendix – Sequence Listing

APPENDIX A – VERSION WITH MARKINGS TO SHOW CHANGES MADE IN THE CLAIMS

1. (Twice Amended) A bone resorption inhibitor composition comprising leukocyte activating protein factor or leukocyte activating protein factor-derived substances having an amino acid sequence of SEQ ID NO. 2, in an amount effective for bone resorption inhibitory activity.

2. (Twice Amended) The bone resorption inhibitor composition according to claim 1, wherein the leukocyte activating protein factor has sequences of amino acid number [1 to 151 or] 19 to 151 of SEQ ID NO. 2.

3. (Twice Amended) The bone resorption inhibitor composition according to claim 1, wherein the leukocyte activating protein factor or leukocyte activating protein factor-derived substances inhibits against osteoclast cell activity.

4. (Twice Amended) The bone resorption inhibitor composition according to claim 1, wherein said substances have an inhibitory activity of more than 80% at a concentration of 10 μg/ml using percent inhibition of pit formation.

5. (Twice Amended) A screening method for bone resorption inhibitor derived substances containing leukocyte activating protein factor or leukocyte activating protein factor-derived substances having an amino acid sequence of SEQ ID NO. 1, which are purified from the source of these substances, or which are prepared by or synthesized [by] based on the information of these

substances, comprising providing said derived substances and determining bone resorption inhibitory activity of the derived substances using percent inhibition of pit formation.

6. (Twice Amended) A method [to produce] of producing bone resorption [inhibitors] inhibitor comprising [introducing] using leukocyte activating protein factor or leukocyte activating protein factor-derived substances having an amino acid sequence of SEQ ID NO. 1 in the production of bone resorption inhibitors.

7. (Twice Amended) A method for bone resorption inhibiting in an animal comprising administering to said animal [,] an effective amount of bone resorption inhibitor derived substances containing leukocyte activating protein factor or leukocyte activating protein factor-derived substances having an amino acid sequence of SEQ ID No. 1.

8. (Amended) The bone resorption inhibitor composition according to claim 2, wherein the leukocyte activating protein factor or leukocyte activating protein factor-derived substances inhibits against osteoclast cell activity.

9. (Amended) The bone resorption inhibitor composition according to claim 2, wherein said substances have an inhibitory activity of more than 80% at a concentration of 10 μg/ml using percent inhibition of pit formation.

10. (Amended) The bone resorption inhibitor composition according to claim 3, wherein

said substances have an inhibitory activity of more than 80% at a concentration of 10 μg/ml using percent inhibition of pit formation.